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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/370,453	08/09/1999	DAN W. DENNEY JR.	GENITOPE-038	8128

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/370,453	Applicant(s) DENNEY, DAN W.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/02 has been entered.

Sequence Disclosure

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN A ***THE SAME TIME PERIOD AS THAT GIVEN FOR REPONDING TO THE PRESENT OFFICE ACTION*** WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

3. Applicant is also advised that a letter requesting that the sequence from a parent application be transferred to the instant application may also be requested. See the following sample letter.

Sample Request to Use Computer Readable Form from Another Application:

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical

computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application.

> The computer readable form in this application, _____, is identical to that filed in Application Number (insert application number) filed (insert filing date). In accordance with 37 CFR 1.821(e), please use the (first-filed, last-filed, or only, whichever is applicable) computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is (included in the originally-filed specification of the instant application or included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable).

Specification

4. Claims 1,3-6,25-32 are objected to because of the following informalities: The claims define the scope of an invention and must particularly point out and distinctly claim the invention, and must be a single sentence starting "I (We) claim:" or "What is claimed is:." Appropriate correction is required.

5. The amendment filed 4/29/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the correction and replacement of "*B-cell*" with "*T-cell*".

Applicant is required to cancel the new matter in the reply to this Office Action.

6. The use of the trademark such as SEPHAROSE, NITEX, FACSCAN (see page 79) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicant is requested to check the specification for any other trademarks and correct as needed.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7.

Claim Rejections Withdrawn

8. The rejection of claims 1,3-6, and 25-30 under 35 U.S.C 103(a), as being obvious over Tao and Levy (Nature 1993; 362:755) and Stevenson *et al* (Ann N.Y. Acad Sci 1995;772:212) in view of Paul (ed.) (Fundamental Immunology 1989 2nd edition pp.1060-1 and 1066-7) is **withdrawn**, pursuant to applicant's arguments , which were persuasive. However, see the new grounds of rejection which follow.

New Claim Rejections

Claim Rejections - 35 USC § 112

9. Claims 1,3-6, and 25-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a multivalent immunogenic composition, does not reasonably provide enablement for a multivalent vaccine. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claimed invention is drawn to a multivalent vaccine composition comprising at least two recombinant variable regions of

immunoglobulin molecules derived from B-cell lymphomas. Because of the term *"vaccine,"* the claims emcompass administration of the claimed composition for treatment of and protection against development of B-cell lymphomas.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that vaccines to cancer are highly unpredictable. Further, it would be extremely difficult to predict which population would benefit from administration of such vaccines. One such example found in the art is Evans *et al* (QJM 1999 Jun;92(6):299-307), wherein Evans *et al* disclose that vaccines at best can only have a therapeutic effect and that *"the notion that a cancer vaccine will replace standard therapeutic strategies in malignant disease still belongs to the realm of fiction."* Furthermore, the art teaches immunogenic compositions but does not teach protecetive effects for the compositions see Stevenson *et al* (Annals of the New York Academy of Sciences 1995 Nov 27;772:212-226, especially page 212)

The amount of direction or guidance present and the presence or absence of working examples: The specification does not teach how to use the instant composition as a therapeutic or prophylactic. No guidance or working examples in the instant application have shown one of skill in the art how to use the claimed vaccines for the treatment or prevention of cancer.

The breadth of the claims and the quantity of experimentation needed: Because the claims encompass in vivo administration of the claimed composition to elicit either a therapeutic or prophylactic immune response and because ht e art teaches that the efficacy of cancer vaccines is highly unpredictable, it would

require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claim1, 3-6, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tao *et al* or Stevenson *et al* in view of de The (Blood Cells 1993;19(3):667-73;discussion 674-5). For the purposes of the present rejection, the claims have been interpreted as drawn to an immunogenic composition comprising variable regions fused to or linked to a cytokine.

Tao *et al* teach a fusion protein that comprises variable regions (both light and heavy chains) obtained from B-cell tumors fused to a cytokine, GM-CSF, wherein the fusion protein augments antigen presentation. Stevenson *et al* teach that idiotypic proteins expressed by B-cells are useful in the production of an protective immune response. Tao *et al* and Stevenson *et al* however do not teach that lymphomas are polyclonal. However, de The does teach that in Burkitts lymphoma, B-cells can undergo polyclonal proliferation.

It would have been *prima facie* obvious to one of skill in the art at the time the invention was made to combine the references of the prior art to devise of a idiotypic immunogenic composition that was multivalent because Tao *et al*, Stevenson *et al* and de The teach of idiotypic immunogenic composition that are polyclonal. The art as taught by de The provides the motivation because de The

discloses the multivalent mature of B-cell lymphomas and discloses possible avenues of treatment using such compositions.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
Art Unit 1642
July 26, 2002